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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,553	07/13/2001	Avi Ashkenazi	10466/39	9211

35489 7590 07/25/2003

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/25/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,553

Applicant(s)

ASHKENAZI ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-46 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-46 and 49 is/are allowed.
- 6) ☒ Claim(s) 39-43, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures and Raw Sequence Listing Error Report .

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DETAILED ACTION

The amendment filed April 7, 2003 (Paper No. 16) has been entered. Claims 39-46, 49-51 are pending and being examined.

5 **Maintained Formal Matters, Objections, and/or Rejections:*****Priority***

The examiner has concluded that the subject matter defined in this application is supported by the disclosure in application PCT/US00/04414 filed February 22, 2000, but is not supported by any of the others because prior to February 22, 2000 the PRO214 polypeptide is not supported by either a specific and substantial asserted utility or a well established utility, and one skilled in the art clearly would not know how to use the claimed invention. Accordingly, the subject matter defined in claims 39-46, 49-51 has an effective filing date of February 22, 2000.

Applicant argues that the gene amplification data disclosed in example 92 and table 8 of the present application was first disclosed in application serial no. 60/099,803, filed September 10, 1998 and establishes patentable utility for the present case. Applicant's arguments have been fully considered but they are not persuasive. The present claims are directed to or encompass the PRO214 polypeptide (SEQ ID NO: 109). The data disclosed in example 92 and table 8 of the present application discloses gene amplification of DNA encoding the PRO214 polypeptide.

The specification asserts at page 222, full paragraph 2, that amplification is associated with overexpression of the gene product, indicating that the polypeptides are useful targets for therapeutic intervention in certain cancers such as colon, lung, breast and other cancers and diagnostic determination of the presence of those cancers. However, no information is provided

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in the gene amplification data regarding the level of expression, activity, or role in cancer of the PRO214 polypeptide. Further, WISP-2 genomic DNA was amplified in colon cancer cell lines and in human colon tumors, but RNA expression was reduced (2- to >30-fold) in 79% of the tumors. See Pennica (u20), Abstract. This evidence indicates that DNA amplification is not always associated with overexpression of the gene product. Consequently, the asserted diagnostic utility of the PRO214 polypeptide requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use, and the increased copy number of PRO214 DNA does not provide a readily apparent use for the PRO214 polypeptide, for which there is no information regarding the level of expression, activity, or role in cancer. The gene amplification data disclosed in example 92 and table 8 of the present application, which was first disclosed in application serial no. 60/099,803, filed September 10, 1998, does not satisfy the utility requirement of 35 U.S.C. § 101 for the polypeptide. Hence, the gene amplification data does not satisfy the how to use requirement of 35 U.S.C. § 112, first paragraph, for the polypeptide.

Applicant refers to an attached declaration by Audrey Goddard. However, the declaration was not attached to the reply filed April 7, 2003 (Paper No. 16) and the declaration is not of record in the present application.

It is noted that in the supplemental application data sheet filed April 21, 2003 (Paper No. 17) Applicant is no longer claiming priority to provisional application serial no. 60/099,803.

Therefore, the disclosure in the 60/099,803 is not germane to the issue of priority in the present application.

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Claim Rejections - 35 USC § 112

Claims 39-43, 50, 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the claims are drawn to a genus of polypeptides defined by biological activity and sequence identity. Applicant's arguments have been fully considered but they are not persuasive. Although the presently amended claims recite "associated with the formation or growth of lung or colon tumor," the claims do not indicate whether an increase, a decrease, or the mere presence of the genus of polypeptides is "associated" with tumor formation. Further, WISP-2 genomic DNA was amplified in colon cancer cell lines and in human colon tumors, but RNA expression was reduced (2- to >30-fold) in 79% of the tumors. See Pennica (u20), Abstract. This evidence indicates that DNA amplification is not always associated with overexpression of the gene product. No information is provided in the present specification regarding level of expression, activity, or role in cancer of the PRO214 polypeptide. The examiner accordingly finds that the species exemplified, identified, or otherwise described with particularity is not representative of the functional genera implied by the structural and functional limitations imposed by the claims, and that the skilled artisan would thus not have recognized that the inventors were in possession of the invention now claimed at the time the application was filed.

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Claim Rejections - 35 USC § 102

Claims 39, 50, 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Ruben (n10).

Applicant argues that Ruben is not appropriate prior art because the effective date of Ruben is 11/18/1999, which is after the effective filing date (9/10/1998) of the present application. Applicant's arguments have been fully considered but they are not persuasive. The present claims are directed to or encompass the PRO214 polypeptide (SEQ ID NO: 109). The data disclosed in example 92 and table 8 of the present application discloses gene amplification of DNA encoding the PRO214 polypeptide. The specification asserts at page 222, full paragraph 2, that amplification is associated with overexpression of the gene product, indicating that the polypeptides are useful targets for therapeutic intervention in certain cancers such as colon, lung, breast and other cancers and diagnostic determination of the presence of those cancers. However, no information is provided in the gene amplification data regarding level of expression, activity, or role in cancer of the PRO214 polypeptide. Further, WISP-2 genomic DNA was amplified in colon cancer cell lines and in human colon tumors, but RNA expression was reduced (2- to >30-fold) in 79% of the tumors. See Pennica (u20), Abstract. This evidence indicates that DNA amplification is not always associated with overexpression of the gene product. Consequently, the asserted diagnostic utility of the PRO214 polypeptide requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use, and the increased copy number of PRO214 DNA does not provide a readily apparent use for the PRO214 polypeptide, for which there is no information regarding level of expression, activity, or role in cancer. The gene amplification data disclosed in example 92 and table 8 of

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the present application, which was first disclosed in application serial no. 60/099,803, filed September 10, 1998, does not satisfy the utility requirement of 35 U.S.C. § 101 for the polypeptide. Hence, the gene amplification data does not satisfy the how to use requirement of 35 U.S.C. § 112, first paragraph, for the polypeptide. Accordingly, the subject matter defined in claims 39-46, 49-51 has an effective filing date of February 22, 2000. Therefore, the effective date of Ruben is before the effective filing date of the present application.

Applicant refers to an attached declaration by Audrey Goddard. However, the declaration was not attached to the reply filed April 7, 2003 (Paper No. 16) and the declaration is not of record in the present application.

It is noted that in the supplemental application data sheet filed April 21, 2003 (Paper No. 17) Applicant is no longer claiming priority to provisional application serial no. 60/099,803. Therefore, the disclosure in the 60/099,803 application is not germane to the issue of priority in the present application.

Claim Rejections - 35 USC § 103

Claims 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koehrer (z10).

Applicant argues that the effective date of Koehrer is after the effective filing date of the present application, and, therefore, Koehrer is not prior art under 35 USC § 102 and is not available under 35 USC § 103. Applicant's arguments have been fully considered but they are not persuasive. The present claims are directed to or encompass the PRO214 polypeptide (SEQ ID NO: 109). The data disclosed in example 92 and table 8 of the present application discloses

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gene amplification of DNA encoding the PRO214 polypeptide. The specification asserts at page 222, full paragraph 2, that amplification is associated with overexpression of the gene product, indicating that the polypeptides are useful targets for therapeutic intervention in certain cancers such as colon, lung, breast and other cancers and diagnostic determination of the presence of those cancers. However, no information is provided in the gene amplification data regarding level of expression, activity, or role in cancer of the PRO214 polypeptide. Further, WISP-2 genomic DNA was amplified in colon cancer cell lines and in human colon tumors, but RNA expression was reduced (2- to >30-fold) in 79% of the tumors. See Pennica (u20), Abstract. This evidence indicates that DNA amplification is not always associated with overexpression of the gene product. Consequently, the asserted diagnostic utility of the PRO214 polypeptide requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use, and the increased copy number of PRO214 DNA does not provide a readily apparent use for the PRO214 polypeptide, for which there is no information regarding level of expression, activity, or role in cancer. The gene amplification data disclosed in example 92 and table 8 of the present application, which was first disclosed in application serial no. 60/099,803, filed September 10, 1998, does not satisfy the utility requirement of 35 U.S.C. § 101 for the polypeptide. Hence, the gene amplification data does not satisfy the how to use requirement of 35 U.S.C. § 112, first paragraph, for the polypeptide. Accordingly, the subject matter defined in claims 39-46, 49-51 has an effective filing date of February 22, 2000. Therefore, the effective date of Koehrer is before the effective filing date of the present application.

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Applicant refers to an attached declaration by Audrey Goddard. However, the declaration was not attached to the reply filed April 7, 2003 (Paper No. 16) and the declaration is not of record in the present application.

It is noted that in the supplemental application data sheet filed April 21, 2003 (Paper No.

5 17) Applicant is no longer claiming priority to provisional application serial no. 60/099,803.

Therefore, the disclosure in the 60/099,803 application is not germane to the issue of priority in the present application.

New Formal Matters, Objections, and/or Rejections:

10

Claim Rejections - 35 USC § 112

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 Claims 39-43, 50, 51 are indefinite because it is unclear if an increase, a decrease, or the mere presence of the polypeptide is "associated" with tumor formation.

Conclusion

Claims 44-46, 49 are allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

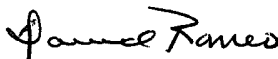
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES	Application No.	Applicant(s)	
	09/904,553	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ A substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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